DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 5, 2014

Depuy Mitek, A Johnson & Johnson Company
% Susan Kagan
Project Manager Regulatory Affairs
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K140896
Trade/Device Name: VAPR® ARCTIC™ Suction Electrode
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: June 13, 2014
Received: June 16, 2014

Dear Ms. Kagan,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

Device Name
VAPR® ARCTIC™ Suction Electrode

Indications for Use *(Describe)*

The VAPR® ARCTIC™ Suction Electrode for use with the VAPR VUE® RF System is intended for resection, ablation and excision of soft tissue, hemostasis of blood vessels and coagulation of soft tissue in patients requiring arthroscopic surgery of the hip.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Joshua C. Nipper -S

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DePuy Mitek Inc. a Johnson & Johnson company — never stop moving™

510(k) SUMMARY

Date Prepared April 7, 2014

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Name of Medical Deice

Classification Name:	Electrosurgical cutting and coagulation device and accessories: 21 CFR 878.4400
Common/Usual Name:	Electrosurgical cutting and coagulation device and accessories
Proprietary Name:	VAPR® ARCTIC™ Suction Electrode
FDA Classification:	II
FDA product code:	GEI

Predicate Device(s)
The proposed **VAPR ARCTIC Electrode** is substantially equivalent to:

- CP90 Electrode: K113545/ K100638
  - (November 11, 2012/ June 18, 2010)
- P50 Electrode: K122425/ K100638/K082643:
  - (November 11, 2012/June 18, 2010)
- Smith and Nephew Eflex Ablator K000691
  - (May 4, 2000)
- Arthrocare Hip ArthroWand: 510(k) # Not Known

Device Description

The VAPR® ARCTIC™ Electrode is a single use, one-piece bipolar suction articulating electrode for use in arthroscopic surgery of the hip. The electrode has a hand-controlled articulating tip to improve access and suction capabilities. This will enhance the efficiency of the electrode and extend the utility of the system by assisting in the removal of bubbles and debris created during activation within the operating site.

The ARCTIC Electrode has been designed to facilitate access and control the delivery of RF energy to the joint space. The plug of the ARCTIC Electrode is designed to fit the VAPR VUE® generator socket only. It has an internal identification capacitor code which automatically adjusts the VAPR VUE Generator to the optimal default and accessible powers and waveforms. If required, the settings for the device can be modified within safe pre-determined limits by accessing the generator or footswitch control. It is intended to be run only off the VAPR VUE electrosurgical generator at pre-determined default settings specific for the device.

Indications for Use

The VAPR® ARCTIC™ Suction Electrode for use with the VAPR VUE® RF System is intended for resection, ablation and excision of soft tissue, hemostasis of blood vessels and coagulation of soft tissue in patients requiring arthroscopic surgery of the hip.

Comparison to Predicate Device

This submission is intended to demonstrate that the ARCTIC Electrode is substantially equivalent to its legally marketed devices.

The Electrode has been carefully compared to legally marketed devices with respect to intended use, essential components and material, performance specifications and technology characteristics.

Comparison to Predicate Devices provided in Table 1.

Table 1: Comparison to Predicate Devices

Component / Feature	VAPR CP90 Electrode	VAPR P50 Electrode	VAPR ARCTIC Suction Electrode	ArthroCare Hip ArthroWand	Eflex Ablator
Manufacturer	DePuy Mitek	DePuy Mitek	**DePuy Mitek**	Arthrocare Sports Medicine	Smith and Nephew
510(k)	K113545 K100638	K122425 K100638 K082643	**Proposed Device**	Not Known	K000691
Indication for Use Statement	The DePuy Mitek VAPR Electrodes for use with the VAPR System are intended for resection, ablation, excision of soft tissue, hemostasis of blood vessels and coagulation of soft tissue in patients requiring arthroscopic surgery of the knee, shoulder, hip, ankle, elbow and wrist.		**The VAPR® ARCTIC™ Suction Electrode for use with the VAPR VUE RF System is intended for resection, ablation and excision of soft tissue, hemostasis of blood vessels and coagulation of soft tissue in patients requiring arthroscopic surgery of the hip.**	The hip ArthroWand with integrated cable is indicated for resection, ablation and coagulation of soft tissue, and hemostasis of blood vessels in arthroscopic procedures	The VULCAN EFLEX Ablator Electrosurgical Probes, in combination with the VULCAN generator Is intended for general surgical use, including orthopedic and arthroscopic applications, for resection, ablation, excision of soft tissue, hemostatis of blood vessels and in coagulating soft tissues in joints including but not limited to the knee, shoulder, wrist, hip, etc.
Fixed vs. Articulating Tip	Fixed	Fixed	**Articulating**	Articulating	Articulating
Degree of Tip Flexion	N/A	N/A	**110 degrees**	90 degrees	100 degrees
Rotating Shaft	No	No	**No**	Yes	No

Tip Configuration	90 degree side effect	End Effect	**End Effect Dome Shape**	Chisel	End Effect Dome Shape
RF Energy	Bipolar	SAME	**SAME**	SAME	Monopolar
Working Length	160mm	SAME	**220mm**	235mm	240mm
Shaft Diameter	3.7mm	SAME	**3.4mm**	2.95mm	3.50mm

Safety and Performance

Verification of the ARCTIC Electrode includes electrical and performance tests to show that the device meets its product specifications over a range of operating conditions. Validation testing includes testing to show the device meets user needs.

Verification testing conforms to the Standards listed in Table 2.

TABLE 2: Standards

Standard / Guidance	**Description**
EN 60601-1:2010	Medical electrical equipment – Part 1: General requirements for safety
EN 60601-2-2:2009	Medical electrical equipment – Part 2-2: Particular requirements for the safety of high frequency surgical equipment
EN 60601-1-2:2007	Medical electrical equipment – Part 1-2: Collateral standards for Electromagnetic compatibility
ISO 10993-1:2009	Biological evaluation of medical devices – Part 1: Evaluation and testing based on externally communicating device with limited contact with tissue/bone dentin
ISO 11137-1:2013	Gamma radiation and shelf life testing
Software Guidance Document (5/11/2005)	Guidance for the content of 510(k) for software contained in medical devices for a MODERATE level of concern

Validation testing includes testing to show the device meets user needs are:

- Shaft bending
- Articulation durability
- Hipot
- Activation

- Polyurethane durability
- Cable tensile
- Suction tube pull
- Fluid ingress
- Distal tip and suction tube sealing
- Active tip and shroud retention
- Lever actuation force
- Articulation angle measurement
- System compatibility
- Dielectric strength
- Suction flow
- Articulation wire pull force
- Lever strength
- Thermal shock
- Thermal margin assessment
- Temperature rise
- Clogging frequency

Clinical Testing

No clinical studies are required to demonstrate safety and efficacy of the device in support of an application for premarket clearance. The ARCTIC Electrodes do not differ from the predicate device in fundamental scientific technology or intended use.

Conclusion

Results of performance and safety testing have demonstrated that the modified device is suitable for its intended use.

Based on the indications for use, fundamental scientific technology, and comparison to the predicate devices, the ARCTIC Electrode is shown to be substantially equivalent to the predicate devices under the Federal Food, Drug and Cosmetic Act.